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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,108	03/01/2002	Sophie Lucas	LUD5611.2 DIV	8397

7590 10/06/2004

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EXAMINER

DAVIS, MINH TAM B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/085,108	LUCAS ET AL.
	Examiner MINH-TAM DAVIS	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 27 July 2004.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 31 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 31 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1)  Notice of References Cited (PTO-892)  
 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5)  Notice of Informal Patent Application (PTO-152)  
 6)  Other: \_\_\_\_\_

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claim 31 is being examined.

The following are the remaining rejections.

### **REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION**

Rejection under 35 USC 112, first paragraph of claim 1 pertaining to lack of a clear written description of the oligonucleotides for use in the claimed method of detecting expression of a MAGE-C3 remains for reasons already of record in paper of 04/09/04.

Applicant argues that Applicant has provided the entire sequence of SEQ ID NO:21, and disclosed that oligonucleotides derived from SEQ ID NO:21 may be used in PCR for amplifying and detect MAGE-C3. Applicant argues that it is within the ability of one of skill in the art to prepare fragments of SEQ ID NO:21 that would encompass nucleotides 175-195 and oligonucleotides that are fully complementary to fragments of SEQ ID NO:21 comprising nucleotides 711-731.

Applicant's arguments set forth in paper of 07/27/04 have been considered but are not deemed to be persuasive for the following reasons:

The language "an oligonucleotide fragment of SEQ ID NO:21" reads on "a sequence comprising an oligonucleotide fragment of SEQ ID NO:21", and thus the claim encompasses a method for detecting the expression of a MAGE-C3 gene using

sequences with unknown structure and function, provided said sequences comprise a fragment of SEQ ID NO:21, comprising nucleotides 175-195 of SEQ ID NO:21, or comprise sequences fully complementary to a fragment of SEQ ID NO:21, comprising nucleotides 711-731 of SEQ ID NO:21.

The rejection could be obviated by amending the claim, for example, to recite "an oligonucleotide consisting of a fragment of SEQ ID NO:21, comprising a sequence of nucleotides 175-195 of SEQ ID NO:21, and an oligonucleotide consisting of a polynucleotide sequence that is fully complementary to a polynucleotide sequence consisting of a fragment of SEQ ID NO:21 comprising nucleotides 711-731 of SEQ ID NO:21".

#### **REJECTION UNDER 35 USC 112, FIRST PARAGRAPGH, SCOPE**

Rejection under 35 USC 112, first paragraph of claim 1 pertaining to lack of enablement for a method for detecting a MAGE-C3 gene, using an oligonucleotide fragment of SEQ ID NO:21 comprising nucleotides 175-195 of SEQ ID NO:21 and an oligonucleotide that is fully complementary to a fragment of SEQ ID NO:21 comprising nucleotides 711-731 of SEQ ID NO:21,under conditions favoring hybridization of said oligonucleotides to an MAGE-C3 coding sequence, and carrying out polymerase chain reaction, remains for reasons already of record in paper of 04/09/04.

A. Applicant argues that Applicant has provided the entire sequence of SEQ ID NO:21, and disclosed that oligonucleotides derived from SEQ ID NO:21 may be used in PCR for amplifying and detect MAGE-C3. Applicant argues that it is within the ability

of one of skill in the art to prepare fragments of SEQ ID NO:21 that would encompass nucleotides 175-195 and oligonucleotides that are fully complementary to fragments of SEQ ID NO:21 comprising nucleotides 711-731.

Applicant's arguments set forth in paper of 07/27/04 have been considered but are not deemed to be persuasive for the following reasons:

The language "an oligonucleotide fragment of SEQ ID NO:21" reads on "a sequence comprising an oligonucleotide fragment of SEQ ID NO:21", and thus the claim encompasses a method for detecting the expression of a MAGE-C3 gene using sequences with unknown structure and function, provided said sequences comprise a fragment of SEQ ID NO:21, comprising nucleotides 175-195 of SEQ ID NO:21, or comprise sequences fully complementary to a fragment of SEQ ID NO:21, comprising nucleotides 711-731 of SEQ ID NO:21.

In view of the above, one would not know how to make the claimed oligonucleotides for use in the claimed method. Further, the claimed method would be non-specific because the claimed oligonucleotides would hybridize to non-related sequences.

B. Concerning the hybridization conditions, Applicant argues that the term "hybridization" was interpreted in isolation and not within the context of any particular method.

Applicant argues that Sambrook et al teach hybridization of guessmers in Northern and Southern hybridization, and not the particular oligonucleotides recited in the amended claims or to their use in PCR. Applicant argues that Sambrook et al

actually support the enablement of the claim, because Sambrook et al teach how to determine conditions that favor hybridization to correct sequences and thus demonstrate that one of skill in the art could readily devise conditions that would favor such correct hybridization.

Applicant's arguments set forth in paper of 07/27/04 have been considered but are not deemed to be persuasive for the following reasons:

It is noted that since the claim does not specify the polymerase chain reaction (PCR) conditions, it is reasonable to interpret the claimed hybridization conditions for the polymerase chain reaction as any conditions, from very low to very high stringency, wherein under very low stringency, the claimed oligonucleotides would hybridize to non-related sequences, as taught by Sambrook et al. Thus although Sambrook et al teach how to determine conditions that favor hybridization to correct sequences under high stringency, this is not germane to the claimed invention, because the claim encompasses very low stringency hybridization conditions for PCR in the claimed method.

It is further noted that the language "determining expression of a MAGE-C3 gene" encompasses "determining expression of variants of MAGE-C3 gene comprising SEQ ID NO:21", using the claimed oligonucleotides. Applicant has not taught what the structure of the variants of SEQ ID NO:21 is, nor how to make such variants, such that they would have the function of SEQ ID NO:21.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D  
PRIMARY EXAMINER



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MINH TAM DAVIS  
September 14, 2004